K010204

AUG 31 2001

stryker
LEIBINGER

4100 East Milham Avenue
Kalamazoo, MI 49001
Phone (616) 323-7700
(800) 253-7370

Device Name:

Trade Name: Stryker Navigation System - Knee Module
Common Name: Image Guided Surgery System
Classification Name: Instrument, Stereotaxic: 21 CFR 882.4560, Class II

Device Sponsor:

Manufacturer: Stryker Corporation
Stryker Leibinger GmbH and Co. KG
Boetzinger Straβe 41
D-79111 Freiburg Germany
Registration No.: 8010177

Distributor: Stryker Corporation
Stryker Leibinger
4100 E. Milham Avenue
Kalamazoo, MI 49001
Registration No.: 1811755

Regulatory Class: Class II

Summary of Safety and Effectiveness:

The Stryker Navigation System is intended as a planning and intraoperative guidance system to enable open or percutaneous image guided surgery. The system is indicated for any medical condition in which the use of image guided surgery may be appropriate, and where a reference to a rigid anatomical structure such as the skull, long bone or vertebra, can be identified relative to medical images. The ENT Module is also indicated for intranasal or sinus use.

The Navigation System – Knee Module is only suitable for use with the:

- Monogram, PassportTM, Xcelerate instruments for tibial, femoral and patellar preparation for total knee arthroplasty of Stryker Howmedica Osteonics, especially for the implantation of
- Duracon®, Interax, Kinemax®, Scorpio® knees.

Dedicated jigs for femoral and tibial alignment will be required.

The Stryker Navigation System is equivalent in intended use, safety, and effectiveness to existing image guided surgery systems begin marketed by companies such as Stryker, Sofamor Danek, and Orthosoft.

The Stryker Navigation System provides precise stereotactic determination of surgical targets using a stereotactic methodology. The three principle features include computer calculation of stereotactic coordinates from the diagnostic images, measurement of stereotactic coordinates

within the surgical field, high-resolution computer display of diagnostic images with stereotactic coordinates indicated. The system is comprised of hardware and software components.

The Stryker Navigation System does not raise any new safety and efficacy concerns when compared to similar devices already legally marketed. Therefore, the Stryker Navigation System is substantially equivalent to these existing devices.

By: Nicole Petty

Nicole Petty
Regulatory Analyst

Dated: 01-18-01

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 1 2001

Ms. Nicole Petty
Regulatory Analyst
Stryker Corporation
Stryker Leibinger
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K010204
Trade/Device Name: Stryker Navigation System - Knee Module
Regulation Number: 882.4560
Regulatory Class: II
Product Code: HAW
Dated: May 25, 2001
Received: June 4, 2001

Dear Ms. Petty:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Workon, M.D.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K010204

Device Name: Stryker Navigation System – Knee Module

Indications For Use: The Stryker Navigation System is intended as a planning and intraoperative guidance system to enable open or percutaneous image guided surgery. The system is indicated for any medical condition in which the use of image guided surgery may be appropriate, and where a reference to a rigid anatomical structure, such as the skull, a long bone or vertebra can be identified relative to medical images. The ENT Module is also indicated for intranasal or sinus use.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The- Counter Use _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010204

(Optional Format 1-2-96)